

REMARKS

I. Status Summary

Claims 38-44 are pending in the present application. As a result of a Restriction Requirement, claims 1-37 were withdrawn from consideration and subsequently canceled.

Applicants kindly acknowledge the withdrawal by the United States Patent and Trademark Office (hereinafter "the Patent Office") of the several bases of objection to the specification presented in the previous Official Action, as well as the withdrawal of several of the rejections from the previous Official Action. Applicants also acknowledge the acceptance of the Abstract by the Patent Office.

Claims 38, 40 and 42 have been rejected under 35 U.S.C. § 112, second paragraph, on several bases.

Claim 44 has been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claim fails to comply with the written description requirement. The Patent Office asserts that there is no support in the specification for the "2,6-dichloro-4-nitroaniline".

Claims 38-40 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claim contain subject matter that was not described in the specification in such a way as to enable one of ordinary skill in the art to which it pertains to make and/or use the invention.

Claims 41-44 have been rejected under 35 U.S.C. § 103 upon the contention that the claims are obvious over Stephens *et al.* (33 Crop Sci 63-66, 1993; hereinafter "Stephens").

Claims 38, 39, 41, and 42 have been amended. New claim 45 has been added. Support for the amendments can be found throughout the specification as filed, including particularly at page 81, lines 5-13. Additional support can be found on page 83, line 11, to page 84, line 10. Additional support can be found at page 94, lines 2-8 and lines 16-19. No new matter has been added by any of the amendments to the claims. Reconsideration of the application as amended and based on the remarks set forth herein below is respectfully requested.

II. Response to Rejections under 35 U.S.C. § 112, Second Paragraph

Claims 38, 40 and 42 have been rejected under 35 U.S.C. § 112, second paragraph, upon the contention that certain terms and phrases used in the claims render the claims indefinite. After carefully consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

II.A. The Phrase "A Low Density Inoculum"

The first aspect of the instant rejection relates to the recitation in claims 38 and 40 relates to the assertion that the phrase "a low density inoculum" is relative and does not state the metes and bounds of the claimed subject matter. Applicants respectfully submit that the claims must be read in view of the specification, and given the teachings of the specification and the knowledge of the skilled artisan, applicants respectfully submit that one of ordinary skill in the art would recognize the nature of a "low density inoculum".

However, in an effort to expedite prosecution of the subject U.S. patent application, claim 38 has been amended by deleting "low density" and inserting a phrase that recites that the inoculum of *Fusarium solani* has an inoculum density of about  $5 \times 10^3$  spore/cm<sup>3</sup> soil or less. Support for the amendments can be found throughout the specification as filed, including particularly at page 81, lines 5-13.

It is thus respectfully submitted that rejection has been addressed with respect to claim 38. It is assumed that claim 40 was rejected because of its dependency from the claim 38. As such it is also respectfully submitted that the rejection has been addressed with respect to claim 40.

II.B. The Phrase "Determining a Level of Resistance"

Claim 42 has been rejected as indefinite upon the contention that the metes and bounds of "determining a level of resistance" are unclear, as is how the method step is accomplished. Applicants respectfully submit that the claims must be read in view of the specification, and further that given the teachings of the specification and the knowledge of the skilled artisan, one of ordinary skill in the art would understand the

metes and bounds of "determining a level of resistance". Additionally, applicants respectfully submit that the specification as filed, when viewed from the perspective and with the knowledge of the skilled artisan, teaches how to determine a level of resistance.

However, in an effort to expedite prosecution of the subject U.S. patent application, claim 42 has been amended to recite determining a level of resistance to soybean sudden death in the soybean plant based on a disease severity value, an infection severity value or both a disease selection value and an infection severity value. It is thus respectfully submitted that rejection has been addressed with respect to claim 42. Support for the amendments can be found throughout the specification as filed, including particularly at page 83, line 11, to page 84, line 10. Additional support can be found at page 94, lines 2-8.

Summarily, then, applicants respectfully submit that as a result of the amendments to the claims in combination with the remarks presented herein, the rejections of claims 38, 40 and 42 under 35 U.S.C. § 112, second paragraph, have been addressed. Accordingly, applicants respectfully submit that claims 38, 40 and 42 are now in condition for allowance. Applicants respectfully solicit a Notice of Allowance to that effect.

III. Response to Claim Rejections Under 35 U.S.C. § 112, First Paragraph

III.A. First Rejection

Claim 44 has been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claim fails to comply with the written description requirement. The Patent Office asserts that there is no support in the specification for the "2,6-dichloro-4-nitroaniline". This rejection is respectfully traversed.

Applicants respectfully direct the Patent Office's attention to Paragraph 0229 of the present U.S. patent application as published. There it is disclosed that the fungistatic antibiotics that can be employed in accordance with the presently disclosed subject matter can include Botran. Botran is a trade name for 2,6-dichloro-4-nitroaniline. See [http://www.osha.gov/dts/chemicalsampling/data/CH\\_221705.html](http://www.osha.gov/dts/chemicalsampling/data/CH_221705.html),

copy attached. Thus, it is believed that the present specification fully supports the recitation of 2,6-dichloro-4-nitroaniline in claim 44.

Accordingly, withdrawal of this rejection of claim 44 is respectfully requested. Allowance of claim 44 is also respectfully requested.

III.B. Second Rejection

Claims 38-40 have been rejected under 35 U.S.C. § 112, first paragraph, upon the contention that the claims encompass subject matter that was not described in the specification in such a way as to enable one of ordinary skill in the art to make and use the invention. The Patent Office asserts that the art distinguishes between low and moderate inoculum levels, and further that Njiti *et al.* (41 Crop Sci 1726, 2001) taught that at low inoculum levels, about 20% of field susceptible lines were identified as resistant. This rejection is respectfully traversed.

Initially, applicants respectfully submit that as a matter of Patent Office practice, the burden rests upon the Patent Office to establish a *prima facie* case of a failure to comply with 35 U.S.C. § 112, first paragraph, with respect to the invention described and claimed in applicants' presumptively enabling patent application. See In re Marzocchi, 58 C.C.P.A. 1069, 439 F.2d 220, 169 U.S.P.Q. 367 (C.C.P.A. 1971). Indeed, 35 U.S.C. §112, first paragraph, requires no more than a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of the claims, and this requirement has clearly been met in the instant U.S. patent application.

In In re Wands, the Court of Appeals for the Federal Circuit as announced eight factors that must be taken into consideration for determining whether undue experimentation would be necessary to practice the invention. In re Wands, 858 F.2d 731 (Fed. Cir. 1988). These so-called *Wands* factors include the quantity of experimentation necessary, the amount of direction or guidance presented, the presence or absence of working examples, the nature of the invention, the state of the prior art, the relative skill of those in the art, the predictability or unpredictability of the art, and the breadth of the claims.

Applicants respectfully submit that when these factors are considered together, they clearly indicate that the specification as filed provides a fully enabling disclosure as to claims 38-40. For example, applicants respectfully submit that the quantity of experimentation that would be required to practice the instantly claimed subject matter is merely that which would be expected to test the resistance to SDS in soybeans. Furthermore, the specification contains numerous working examples that show the exact procedures to be followed in performing such tests.

Example 7, pages 83-84, of the present U.S. patent application is referenced (Paragraph 209 in the present U.S. patent application as published), which states that the heritability of disease severity (DS) in the greenhouse was 63%, 35%, and 34% for the low, medium and high inoculum densities respectively. Infection severity (IS) heritability was 66 percent. The SDS susceptible group means for DS and IS at low inoculum density were significantly higher than those of the moderate and resistant groups (Table 14 of the present U.S. patent application). DS and IS values from the low inoculum density treatment were significantly correlated with both field DS and disease index (DX) (Table 16 of the present U.S. patent application). When both greenhouse DS ( $=<1.9$ ) and IS ( $=<400$ ) were used as selection criteria for field resistance, all the SDS field susceptible and eight of the 10 field moderate genotypes were eliminated but only four of the 10 partially field resistant genotypes were eliminated (Table 15 of the present U.S. patent application). These results demonstrate that the use of DS and IS values obtained at low inoculum densities, such as about  $3 \times 10^3$  spore per cubic centimeter of soil, is an effective method of selection of soybean genotypes with high resistance to SDS. Both DS and IS from the low inoculum density assays were significantly ( $P=<0.05$ ) associated with DNA markers that identify major SDS resistance QTLs in the field (Table 17 of the present U.S. patent application). These results show that a low inoculum greenhouse assay can be used to supplement marker-assisted selection for partial field resistance to SDS.

Continuing with the instant rejection, the Patent Office cites Njiti et al., 2001 for the proposition that it would require undue experimentation to "screen through a myriad of soybean lines both susceptible and resistant to SDS using a low inoculum level" and

also for the proposition that it required almost three and half years of additional experiment to "perfect the method".

Njiti et al., 2001 is a post-priority date publication that relates to the presently disclosed methods as recited in claims 38-40. Applicants respectfully submit that even assuming *arguendo* that Njiti et al., 2001 does teach that at low inoculum levels about 20% of field susceptible lines were identified as resistant, the corresponding successful identification rate is a vast improvement over tests that were available in the art at the time of priority date of the present U.S. patent application, i.e. 1997. To elaborate, Figure 1 of Njiti et al., 2001 clearly shows that low inoculum densities provide a linear correlation with field response, and also provide  $r^2$  values and the elimination of susceptible lines. Thus, contrary to the assertions of the Patent Office, Njiti et al., 2001 supports the presently disclosed methods as recited in claims 38-40.

Summarily, then, applicants respectfully submit that the Patent Office has not met its burden in establishing a *prima facie* case of a lack of enablement with respect to claims 38-40. Applicants respectfully request that the rejection of claims 38-40 under 35 U.S.C. § 112, first paragraph, be withdrawn, and the claims allowed at this time.

*Response to Rejection Under 35 U.S.C. § 103 Based On Stephens et al.*

Claims 41-44 have been rejected under 35 U.S.C. § 103(a), upon the contention that the claims are obvious over Stephens et al. (33 Crop Sci 63, 1993; hereinafter "Stephens et al."). The Patent Office contends that Stephens et al. discloses a method of characterizing resistance to soybean SDS in a soybean plant comprising isolating roots from a soybean plant infected by *Fusarium solani*, culturing the root on a culture plant including a restrictive growth medium containing tetracycline, determining "root infection severity by evaluating the colony forming units on said culture plate" and characterizing resistance to soybean SDS in said soybean plant and determining a level of resistance to SDS in the soybean plant. After carefully consideration of the rejection and the Patent Office's bases therefor, applicants respectfully traverse the rejection and submit the following remarks.

Applicants respectfully submit that in order to render a claim obvious under 35 U.S.C. § 103(a), the prior art must disclose or suggest each and every element of the claim, as well as motivate the skilled artisan to modify the reference(s) as suggested by the Patent Office to arrive at the claimed invention with a reasonable expectation of success.

Applicants respectfully submit that the Patent Office has not met its burden of establishing a *prima facie* case of obviousness over the cited reference because the cited reference does not disclose each and every element of the presently claimed subject matter, or provide a motivation to modify the subject matter disclosed therein with a reasonable expectation to reach the presently claimed subject matter.

Claim 41 presently recites a method of characterizing resistance to soybean sudden death syndrome in a soybean plant, comprising isolating root pieces from a soybean plant infected by *Fusarium solani*; culturing the root pieces on a culture plate including a restrictive growth medium that provides for slow fungal growth and restricted bacterial growth; determining root infection severity by statistically evaluating the number of *Fusarium solani* colony forming units on said culture plate, wherein the statistically evaluating comprises counting the number of CFU, and expressing the number of CFU as a percentage of a total number of root pieces; and characterizing resistance to soybean sudden death syndrome in said soybean plant based on said determined root infection severity.

There is no disclosure in Stephens of quantifying the number of CFU, and particularly no disclosure of statistically evaluating the number of CFU by counting the number of CFU, and expressing the number of CFU as a percentage of a total number of root pieces, as recited in claim 41. Moreover there is no disclosure of using a restrictive media in Stephens to restrict overgrowth of the culture plates by faster growing non-pathogenic fungi and bacteria. Thus, claim 41, when considered as whole, is believed to be patentably distinguished over the disclosure of Stephens.

In summary, applicants respectfully submit that the Patent Office has not presented a *prima facie* case of obviousness of claim 41. Thus, applicants respectfully submit that claim 41 is in condition for allowance, and respectfully request a Notice of

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Allowance to that effect. Claim 42-44 are ultimately dependent on patentably distinguished claim 41. As such, applicants respectfully submit that claims 42-44 are in condition for allowance in view of their dependency from patentably distinguished claim 41, and respectfully request a Notice of Allowance to that effect.

*Discussion of New Claim*

New claim 45 has been added. Support can be found at page 94, lines 16-19 of the subject U.S. patent application as filed.

New claim 45 is believed to be patentable over the art cited against claims 41-44 for the reasons described hereinabove with regard to claims 41-44. Additionally, claim 45 recites that at least one of the one or more bacteriocidal or bacteriostatic antibiotics is rifampicin.

Applicants respectfully submit that none of the cited art discloses the use of a medium that contains rifampicin. Accordingly, applicants respectfully submit that claim 45 is in condition for allowance, and respectfully solicit a Notice of Allowance to that effect.

**CONCLUSION**

In light of the above amendments and remarks, it is respectfully submitted that the present application is now in proper condition for allowance, and an early notice to such effect is earnestly solicited.

If any small matter should remain outstanding after the Patent Examiner has had an opportunity to review the above Remarks, the Patent Examiner is respectfully requested to telephone the undersigned patent attorney in order to resolve these matters and avoid the issuance of another Official Action.

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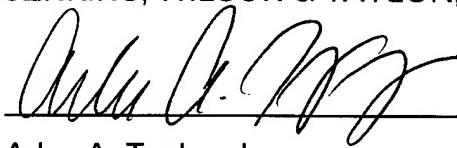
DEPOSIT ACCOUNT

The Commissioner is hereby authorized to charge any fees associated with the filing of this correspondence to Deposit Account No. 50-0426.

Respectfully submitted,

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# EXHIBIT A



## Chemical Sampling Information Botran

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### General Description

**NAME:** Botran

**SYNONYM(s):** 2,6-Dichloro-4-Nitroaniline; DCNA; Bortran

**IMIS:** B585

**CAS:** 99-30-9

**NIOSH:** RTECS BX2975000; 8178

### Exposure Limits

### Health Factors

### Monitoring

#### **PRIMARY SAMPLING/ANALYTICAL METHOD (SLC1):**

**MEDIA:** Glass Fiber Filter (37 mm)

**MAX V:** 400 Liters    **MAX F:** 1.0 L/min

**ANL 1:** High Performance Liquid Chromatography; HPLC/U.

**REF:** 2 (OSHA In-house File)

**CLASS:** Not Validated

**COND:** Column: C18 Mobile Phase:70:30 Methanol:Water

Detector Wavelength: 254 or 350nm Detection Limit: 0.01 mg/m  
3

**WIPE:**

Yes, with Glass Fiber Filter.

**BULK METHOD:**

Limit the amount of bulk submitted to one gram or one mL.

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Revision Date: 08/24/1992

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